

Rec'd PCT/PTO 03 MAR 2005

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference HeL/GB 51058	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE 2003/001360	International filing date (day/month/year) 02.09.2003	Priority date (day/month/year) 03.09.2002
International Patent Classification (IPC) or national classification and IPC A61L 31/16, A61K 31/6615, A61P 9/10		
Applicant BIONERIS AB et al		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
- This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 24.03.2004	Date of completion of this report 24.11.2004
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Erika Stenroos/Els Telephone No. +46 8 782 25 00

Form PCT/IPEA/409 (cover sheet) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/001360

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE 2003/001360

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-16</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	_____	YES
	Claims	<u>1-16</u>	NO
Industrial applicability (IA)	Claims	<u>1-16</u>	YES
	Claims	_____	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: US5383928

D2: WO9749408

The objective of the claimed invention is to provide a coated stent for implantation in human vessels for creating and sustaining openings there, and for preventing restenosis thereof after implantation. The stent is coated with a compound containing a high density, negatively charged domain of at least three vicinally oriented phosphorous-containing radicals.

D1 pertains a stent which is coated with a compound capable of inhibiting cell growth in an arterial wall or lumen into which the stent has been inserted.

D2 refers to the use of a compound containing a high density, negatively charged domain of at least three vicinally oriented phosphorous radicals for the preparing of a medicament providing a growth factor modulating activity in mammals. The compound interacts with the regions of the growth factor that are essential for the dimerization and subsequent activation, but also for the interaction between the growth factors and their cellular receptors.

D1 is considered to be closest prior art. The difference between D1 and the claimed invention is that the drug/molecule specified for preventing restenosis in D1 is not the same.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Nevertheless, in D2 the same molecule as in the claimed invention is used as a growth factor inhibitor, but in dosage forms comprising tablets, granules, solutions or suspensions. To use a compound with well known effects in a different manner, i.e. in a coating instead of a tablet, that does not lead to that an unexpected effect has been achieved is not considered to be inventive. Therefore, it must be considered as an obvious application of known art to use the compound from D2 for use in the same manner as in D1.

According to the statement above, claims 1-16 are not considered to involve an inventive step.